

REMARKS

Claim 18 stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Claims 9 and 18 stand rejected as allegedly being indefinite. Lastly, Claims 9-24 stand rejected as being obvious over Wilson, US Patent No. 5,573,515. Applicants have amended independent Claims 9, 12 and 18 and submit that the pending claims are patentable over the cited prior art in view of the following remarks.

Applicants submit herewith a Request for Continued Examination so that the present After Final Amendment will be entered and considered by Examiner.

Amended Claim 9 recites a method for performing a filling sequence to fill a syringe with contrast media through a fill tube coupling the syringe to the contrast media. In this method, contrast media is drawn into the syringe through the fill tube at a first fill rate. Subsequently, substantially all air is expelled from the fill tube. Along with this expulsion of air from the filled tube, at least some of the contrast media from within the syringe is also expelled through the fill tube. Thereafter, the syringe is filled at a second fill rate to fill the syringe with the desired fill volume of contrast media; this second fill rate being faster than the first fill rate.

For example, in one embodiment, a small amount of contrast media is pulled into the syringe at a slow enough rate (e.g., a first fill rate) so as not to aerate the fluid. Once the small volume of contrast media is in the syringe, the injector system automatically (or the operator, manually) reverses the direction of the injector ram so as to substantially expel substantially all air from the fill tube. At least some of the contrast media from the syringe is also expelled through the fill tube during this expulsion. Thereafter, with substantially no air in the syringe and fill tube, the syringe can be filled at a faster fill rate (e.g., a second fill rate) to fill the syringe to the desired fill volume with a reduced risk of introducing bubbles due to aeration (see Page 12, line 20 through Page 13, line 20, for example).

By comparison, Wilson is directed to an injector having a "Set Up/Fill End" switch which is activated so that the user will be notified to place a syringe in a syringe holder. Thereafter, the plunger is moved to its full forward position expelling air from within the syringe. The contrast reservoir is then connected to the syringe, and the plunger is then retracted at a **set rate** (e.g., 10 ml/sec.) so as to fill the syringe to the maximum syringe volume. A purge switch is then activated to move the plunger forward to expel air through a

top port. The forward movement of the plunger is limited and stopped when a predetermined pressure within the syringe is reached (see Col. 10, lines 4-30 and Col. 12, line 59 through Col. 13, line 51).

In short, Wilson simply teaches that contrast media is drawn into an empty syringe at a **set rate** to fill the syringe to the maximum syringe volume. Thereafter the air is expelled from the syringe.

Wilson is completely silent with respect to an additional step of filling the syringe subsequent to the expulsion of air. As such, Wilson is also silent with respect to performing this subsequent filling step at a fill rate that is faster than the fill rate of the initial filling step. Rather, the injector of Wilson always fills the syringe in a single filling step at one fill rate which is a **set rate** (see Col. 10, lines 4-11). Consequently, Wilson is completely silent to first and second fill rates as recited in Claim 9. The passages relied upon by the Examiner to support what is characterized in the Office Action as "flow rate changeable" refers to *Injection* rates and not *fill* rates. As such, Wilson is also completely silent with respect to a second fill rate that is faster than a first fill rate as recited in Claim 9.

Claim 12 is directed to a method for changing contrast media containers during a syringe filling sequence. In this method, a syringe is filled at at least one of a first fill rate and a second fill rate through a fill tube coupled between the syringe and a first contrast container. This filling step is paused when the first contrast container is substantially emptied. The first contrast container is then replaced with a second contrast container, and the fill tube is coupled between the syringe and the second contrast container. Next, substantially all air is expelled from the fill tube coupled between the syringe and the second contrast container. During this expulsion of the air, at least some of the contrast media is expelled from the syringe, through the fill tube, and into the second contrast container. After the expulsion of air and contrast media, filling the syringe may be resumed, but this time from the second contrast container at the second fill rate, which is faster than the first fill rate.

For the reasons set forth above with respect to the rejection of Claim 9 over Wilson, Applicants submit that Wilson taken alone, or in any combination with the other prior art of record, fails to fairly teach or suggest a method of changing contrast media containers during a syringe filling sequence. Further, Wilson fails to teach or suggest expelling contrast media

that was acquired from a first contrast container into a second contrast container using the syringe that is being filled during a syringe filling sequence. Wilson also fails to teach or suggest an initial filling, followed by an expulsion, followed by a subsequent resumption of filling. Consequently, the rejection should be withdrawn.

Claim 18 recites a syringe filling method for a contrast media injector system. In this method, medical fluid is drawn into a syringe at a first fill rate and, thereafter, at least some of the medical fluid is expelled from the syringe. After the medical fluid is expelled from the syringe, the syringe is filled at a second fill rate that is faster than the first fill rate.

For the reasons set forth above with respect to the rejections of Claims 9 and 12, Applicants submit that the rejection of Claim 18 is improper and should be withdrawn.

In the rejections of Claims 9-21, 23 and 24, it is again worth noting that the Examiner reference to the adjustable flow rates of Wilson (see Page 4 of Office Action) refer to the maximum flow rate that the system can reach during an *injection* procedure and not to a *fill* rate that the system can reach during a syringe *filling* sequence.

New claim 32 is also directed to a method of operation for a contrast media injector system. In this method, an initial volume of medical fluid is drawn into a syringe of a contrast media injector system at a first fill rate. Next, at least some of the medical fluid is expelled from the syringe. Thereafter, the syringe is filled with medical fluid at a second fill rate that is faster than the first fill rate. Further, a total volume of medical fluid in the syringe after this filling is greater than the initial volume that was drawn into the syringe.

In light of the foregoing, it is believed that all pending claims are in condition for allowance. In such, the Office is respectfully requested to provide written affirmation of the same. Should the Examiner consider issuing any action other than the full Notice of Allowance, the Examiner is respectfully requested to contact the undersigned by telephone to discuss prior to issuing such action.

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In accordance with 37 C.F.R. §1.17(e), please see the electronic fee calculation sheet for the Request for Continued Examination charge in the amount of \$810.00. In accordance with 37 C.F.R. §1.16(i), please see the electronic fee calculation sheet for the extra claims fees in the amount of \$350. Lastly, in accordance with 37 C.F.R. §1.16(h), please see the electronic fee calculation sheet for one extra independent claim in the amount of \$210. In addition, please feel free to charge any additional fee deemed necessary for entry of this paper or credit any overpayment to Deposit Account 23-3000.

Respectfully submitted,

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